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(12) EUROPEAN PATENT APPLICATION

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(54) Medical apparatus for endoscopic surgery.

(57) A medical device for endoscopic access of a body cavity and a method of percutaneously placing inner and outer access sheaths of the device into the body cavity. The medical device includes inner and outer access sheaths and a dilator which is inserted into the outer sheath and has a shoulder or a shoulder piece for abutting against the proximal end of the outer sheath. The device also includes a wire guide that is percutaneously inserted into the body cavity via an introducer needle. The dilator and outer sheath are placed over the wire guide to dilate the puncture site and introduce the dilator and outer sheath into the body cavity. The dilator comprises an elongated cylindrical member having a passageway opening distally from the conically-shaped distal end and from an outside lateral wall of the dilator about the proximal end. The dilator also includes an end cap which is utilized to force the dilator and the outer sheath through the puncture site and into the body cavity. After positioning in the body cavity, the dilator and wire guide are removed through the outer sheath. The inner sheath is then inserted through the outer sheath into the body cavity. The proximal ends of both the inner and outer sheaths include seals for maintaining insufflation of the body cavity. The inner sheath includes a shoulder piece having a chamber and a side port for connection to an insufflation gas line.

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This invention relates to medical devices for performing endoscopic surgery.

It is desirable to perform minimally invasive endoscopic procedures that utilize percutaneous access sheaths such as a percutaneous cholecystectomy, or a percutaneous cholelithotomy.

According to the present invention there is provided medical apparatus as defined in claim 1 or 2.

The surgeon typically utilizes an introducer needle to access and insufflate the peritoneal cavity via the umbilicus. A wire guide is introduced through the needle, and the needle is removed, leaving the guide in place. The dilator advantageously includes a hollow passageway for the wire guide.

The dilator passageway opens laterally from a shoulder to permit the wire guide to pass therefrom and not interfere with the surgeon's introduction of the access device.

Brief description of the drawings

FIG.1 depicts the medical device of the present invention;

FIG.2 depicts a cross-sectional view of one aspect of the dilator and wire guide of FIG.1;

FIG.3 depicts a cross-sectional view of another aspect of the dilator of FIG.1;

FIG.4 depicts a partial cross-sectional view of the outer access sheath of FIG.1;

FIG.5 depicts a partial view of the inner access sheath of FIG.1; and

FIGs.6-8 depict the method of percutaneously placing the inner and outer access sheaths of FIG.1 into a body cavity.

Depicted in FIG.1 is a preferred illustrative embodiment of medical device 100 for percutaneously accessing a body cavity for an endoscopic surgical procedure. The medical access device comprises dilator 101, outer sheath 102, and inner sheath 103. Dilator 101 is positioned in the hollow passageway of outer sheath 102 and percutaneously inserted into a body cavity via wire guide 104. The device 101 dilates rather than cuts the patient. By way of example, the surgeon introduces an introducer needle into the peritoneal body cavity via the umbilicus. The peritoneal cavity is typically insufflated with a gas such as carbon dioxide, and the wire guide 104 is inserted into the insufflated body cavity via the puncture site formed by the introducer needle. Dilator 101 is inserted into outer sheath 102 and placed over wire guide 104. The puncture site is dilated, and the dilator and outer sheath are introduced into the insufflated peritoneal cavity by applying a force to end cap 107 of the dilator. The dilation of the puncture site is enhanced by first wetting hydrophilic material 105 coating the conically-shaped distal end 106 of the dilator. The dilator and wire guide are removed through the outer sheath positioned in the body cavity, and the inner sheath 103 is positioned in the passageway of the outer sheath. Insufflation of the body cavity is maintained through side ports 108 laterally positioned about the proximal end of the inner access sheath.

Depicted in FIG.2 is a cross-sectional view of dilator 101 with wire guide 104 extending through passageway 112. Dilator 101 comprises an elongated member 109 having a conically-tapered distal end 106, proximal end 110, and outside lateral wall 111 extending between the two ends. Hollow passageway 112 extends longitudinally in the elongated member and opens distally from the tapered distal end at opening 113 and laterally from the outside lateral wall about the proximal end. Passageway 112 is sized for extending wire guide 104 therethrough as shown. End cap 107 is positioned at and extends from proximal end 110 of the elongated member. This end cap fits easily into the palm of the surgeon's hand or is easily grasped by the fingers to apply force to the dilator for introducing the tapered distal end into the puncture site over wire guide 104. The dilator also includes a well-known hydrophilic material 105 coating the tapered distal end, which is wetted with, for example, saline to ease dilation of the puncture site. The elongated member further includes shoulder 114 positioned about the proximal end of the elongated member, which is sized for abutting against the proximal end of outer sheath 102. Shoulder 114 fixedly positions the dilator against the proximal end of outer sheath 102 when the dilator and outer sheath are being introduced into the peritoneal body cavity via the puncture site.

Depicted in FIG.3 is another aspect of dilator 101 including a first elongated member 156 having conically-tapered distal end 106, proximal end 110, and side lateral wall 115 extending between the two ends. Hollow passageway 116 extends longitudinally between ends 106 and 110. The dilator further includes a second elongated member 117 positioned within passageway 116 and having a passageway 118 opening from conically-tapered distal end 106 distally and from side lateral wall 115 laterally about proximal end 110. End cap 107 is attached and extends from the proximal end of first elongated member 156 via sleeve 119. Sleeve 119 is attached about the proximal end 110 of the first member and to the end cap and has a lateral opening 120 communicating with the passageway of elongated member 117.

First and second elongated members 156 and 117 are comprised of a well-known rigid, thermoplastic material such as polyvinylchloride having a durometer of approximately 90 on the Shore A scale. Elongated member 156 comprises a 38 French polyvinylchloride tube approximately 25cms in length. Second member tube 117 comprises a 28 French polyvinylchloride tube also approximately 25cms in length. The second member tube is inserted in passageway 116 of the first member tube with a mandril

inserted into passageway 118 of the second tube. The two distal ends are heated to melt the two distal ends together to form conically-tapered distal end 106 approximately 5cms in length. The proximal end of the inner member tube is glued to the outside lateral wall about the proximal end of the outer member tube. Polyvinylchloride sleeve 119 is placed over the proximal end of the outer member tube attached thereto using a well-known medical grade adhesive. Opening 120 is formed in the sleeve to permit communication with passage 118 of the inner member tube. The opening and inner member passageway are large enough to permit a commercially available wire guide having, for example, a 0.0965cms (0.038") outer diameter to pass readily therethrough. End cap 107 is a circular knob having an outer diameter of approximately 25mms and a length of approximately the same dimension which is inserted into the opening of the sleeve and attached thereto using again, for example, medical grade adhesive. A well-known hydrophilic material 105 coats the conically-tapered distal end of the dilator.

The dilator depicted in FIG.2 is comprised of, for example, the same thermoplastic polyvinylchloride material having approximately the same dimensions as the dilator of FIG.3.

Depicted in FIG.4 is outer sheath 102 of FIG.1. Outer sheath 102 comprises a well-known thermoplastic material tube 121 such as polytetrafluoroethylene having a slick outer surface. This thermoplastic material is also a rigid thermoplastic having a durometer of approximately 90 on the Shore A scale. Tube 121 has a tapered distal end 122, a flared proximal end 123 at the opposite ends of the passageway 124 extending longitudinally through the tube. The outer sheath tube is approximately 15cms in length and has an inner diameter of 38 French to position dilator 101 therethrough. Fitting 125 is attached to proximal end 123 of the outer sheath tube. Fitting 125 is comprised of three acetal polymer components 126,127, and 128. Circular T-shaped sleeve 127 with annular rings 129 and 130 is pushed into flared proximal end 123. Lock ring 126 is press-fitted over the outside of flared proximal end 123 to attach fitting 125 to inner sheath tubing 121. Beveled annular end cap 128 is positioned as shown to fit over the T-shaped sleeve 127 to position silicon material seal 131 therebetween. Well-known medical grade adhesive affixes beveled end cap 128 to T-shaped sleeve 127. Silicon material seal 131 has an approximate 9mms aperture 132 therein which seals against the outside lateral wall of dilator 101 when the dilator is inserted into passageway 124 of the outer sheath. When inserted therein, the proximal end of sleeve 119 engages the silicon seal and abuts against edge 133 of the T-shaped sleeve 127. This fixedly positions the outer sleeve with respect to dilator 101. Likewise shoulder 114 also abuts against seal 131 and passage 133 of the T-shaped sleeve, again to affix the relative position of the dilator with respect to the outer sheath. The polytetrafluoroethylene material of the outer sleeve tube has a slick surface 134 for engaging and sliding through the dilated puncture site when distal end 122 comes in contact therewith.

Depicted in FIG.5 is inner sheath 103 of FIG.1. The inner sheath is approximately 15cms in overall length and comprises an optically clear, very rigid thermoplastic material tube 135 having an extremely high durometer. Such a thermoplastic material is cellulose acetate butyrate. Inner sheath tube 135 is approximately 15.5cms in length and has an outer diameter of 1.262cms (0.497") and an inner diameter of 1.08cms (0.426"). The inner sheath tube has a tapered distal end 136 and a proximal end 137 at opposite ends of hollow passageway 138 extending longitudinally in the tube. The sheath is sized for positioning within the passageway of outer sheath 102 and has a hollow passageway sized to permit the use of endoscopic instruments up to 10mms in diameter. The inner sheath also includes shoulder piece 139 having a distal neck 140 that is positioned into the proximal end 137 of the inner sheath tube. Medical grade adhesive 141 and 142 are utilized to cement the two pieces together. The larger diameter shoulder 143 is positioned about the proximal end of the inner sheath and is sized for abutting against the proximal end of the outer sheath. Passageway 138 extends through shoulder piece 139. Side port 144 laterally extends from the shoulder piece and communicates with passageway 138. The port is flanged for securing a Luer lock fitting of an insufflating line thereto. First seal 145 is positioned at the proximal end of the shoulder piece and includes criss-crossed slits 146 and 147 for permitting passage of endoscopic instruments therethrough and forming a seal thereabout. These slits communicate with passageway 138 of the inner sheath. The second flexible seal 148 is also attached about the proximal end of the shoulder piece and has an aperture 149 formed therein adjacent to the criss-crossed slits for positioning endoscopic instruments placed therethrough. The aperture is positioned against the slits to further facilitate a gas-tight seal against endoscopic instruments inserted therethrough. The second seal is attached to the proximal end of the shoulder piece with a polyethylene shrink tube 150 as shown.

Depicted in FIGs.6-8 is the method of percutaneously placing outer and inner access sheaths 102 and 103 into body cavity 151 through abdominal wall 152 with the use of wire guide 104 and dilator 101. The method comprises introducing wire guide 104 percutaneously into body cavity 151 through puncture site 153 as depicted in FIG.6. Dilator 101 is positioned into the passageway of outer sheath 102 with shoulder 114 abutting against the proximal end of the outer sheath. The dilator and outer sheath are

placed over wire guide 104 and inserted into the puncture site. Tapered distal end 106 dilates the puncture site as a force is applied to end cap 107 of the dilator. Saline is applied to wet hydrophilic material 105 coating the tapered distal end. The conically-shaped distal ends dilate the puncture site atraumatically to the diameter of the dilator and outer sheath.

Force is continually applied to end cap 107 to fully dilate puncture site 153 to the outer diameters of dilator 101 and sheath 102. When the dilator and the distal end of the outer sheath are positioned in body cavity 151 through the abdominal wall and puncture site, the dilator and wire guide are removed from the body cavity through the outer sheath.

After the wire guide and dilator are removed from the passageway of the outer sheath, inner sheath 103 is inserted through passageway 124 of outer sheath 102. The inner sheath is introduced into the body cavity by way of the outer sheath with seal 131 positioned at the proximal end of the outer sheath preventing the escape of insufflating gas from body cavity 151. Typically a supply line 154 is attached to side port 144 of the inner sheath to supply the peritoneal body cavity with carbon dioxide gas for maintaining insufflation of the body cavity.

When the inner sheath is fully inserted into the outer sheath, shoulder piece 139 abuts against the proximal end of outer sheath fitting 125 as depicted in FIG.8. The distal end of the inner sheath will typically extend a short distance about the distal end of the outer sheath. When so positioned, seals 145 and 148 of the inner sheath along with the seal at the proximal end of outer sheath prevent the escape of insufflating gas from the body cavity. Insufflating gas line 154 also continues to supply insufflation gas to the peritoneal body cavity 151. As shown, endoscope 155 is introduced through the inner sheath through seals 145 and 148 into the peritoneal cavity for providing a viewing space through which the surgeon can view the cavity during a surgical procedure. One or more of these inner and outer access sheaths may be used to penetrate the peritoneal body cavity to permit the surgeon to introduce other endoscopic surgical instruments to perform a particular procedure. The inner sheath may also be removed from the outer sheath to permit larger pieces of tissue or organs to be removed directly through the outer sheath.

It is contemplated that the outer sheath may also include a side port having one or more seals at its proximal end for cooperating with the dilator to insert the outer sheath into a body cavity. The dilator would be removed and endoscopic surgical instruments inserted solely through the outer sheath with the seals and insufflating line attached to the proximal end thereof. This medical device would also be inserted using a wire guide percutaneously inserted into the cavity. The outer diameter of a modified device is also contemplated to be smaller to provide for endoscopic instrument introduction. It is further contemplated that the dilator passageway opens at the proximal end of the elongated member or end cap.

Claims

1. Medical apparatus for endoscopic surgery comprising: an elongated member having a tapered first distal end, a first proximal end, and an outside lateral wall extending between said first ends; a first passageway extending longitudinally in said member and opening from said tapered first distal end distally and from said outside lateral wall about said first proximal end; and an end cap fixed to and adjacent to said first proximal end of said elongated member.

2. Medical apparatus for endoscopic surgery, comprising a first elongated member (101) having a tapered first distal end (106) for penetrating a patient's skin (152) and dilating the location of entry, and said member also having a proximal end with means (107) for imparting force to facilitate the penetration and dilation, characterised by an outer sheath (102) arranged upon the penetration to surround part of the first member, the outer dimensions of the first member and the inner dimensions of the outer sheath in the region of overlap being designed to permit withdrawal of the first member, said outer sheath also having a tapered distal end (122) for facilitating penetration by the outer sheath of the patient's skin prior to withdrawal of the first member.

3. Medical apparatus according to claim 2, characterised in that the proximal end of the outer sheath has a flexible seal (131) designed to maintain its seal during and after withdrawal of the first member, and optionally to provide a seal upon insertion of further apparatus or instrument(s).

4. Medical apparatus according to claim 2 or 3, characterised in that the first member and/or the outer sheath is provided with means (114) for limiting the said overlap.

5. Apparatus according to claim 2,3 or 4, further characterised by an inner sheath (103) adapted to be inserted within the outer sheath after withdrawal of the first member, means (143) being provided for limiting the degree of insertion, said inner sheath being with or without a side port (144) communicating with a passageway (138) through the inner sheath, and/or a flexible seal (145 to 149) at the proximal end of the inner sheath for providing sealed access to the pas-

sageway therein.

6. Medical apparatus for endoscopic surgery, comprising: an outer sheath (102) having a distal end (122), a proximal end (123), and a first hollow passageway (134) extending longitudinally between said first ends; and an inner sheath (103) having a distal end (136), a proximal end (139) a second hollow passageway (138) extending longitudinally between the ends, and a lateral opening (144) positioned about the proximal end and communicating with hollow passageway of the inner sheath, said outer sheath including a first seal (131) attached about its proximal end and having an aperture (132) sized for sealing around said inner sheath when said inner sheath is positioned within the passageway of the outer sheath.

7. Apparatus of claim 3 or 6, characterised in that said inner sheath includes a flexible seal (145) attached about its proximal end and having a slit (146) communicating with the passageway therethrough.

8. Apparatus of claim 7, characterised in that said inner sheath comprises a second flexible seal (148) attached about the proximal end and having an aperture (147) positioned adjacent said slit.

9. Apparatus according to any one of claims 2 to 8, characterised in that the first member has a passageway substantially therethrough for accommodating a wire guide.

10. Apparatus according to any one preceding claim, characterised in that the outer surface of the first member and the outer sheath has a hydrophilic material coating.

11. A method of percutaneously placing inner and outer access sheaths into a body cavity, comprising: introducing a wire guide percutaneously into said body cavity through a puncture site; dilating said puncture site with a dilator and said outer sheath placed over said wire guide; positioning said dilator and the distal end of said outer sheath into said body cavity through said dilated puncture site; removing said dilator and wire guide from said body cavity through said outer sheath; and introducing said inner sheath into said body cavity through said outer sheath when positioned in said cavity through said dilated puncture site.

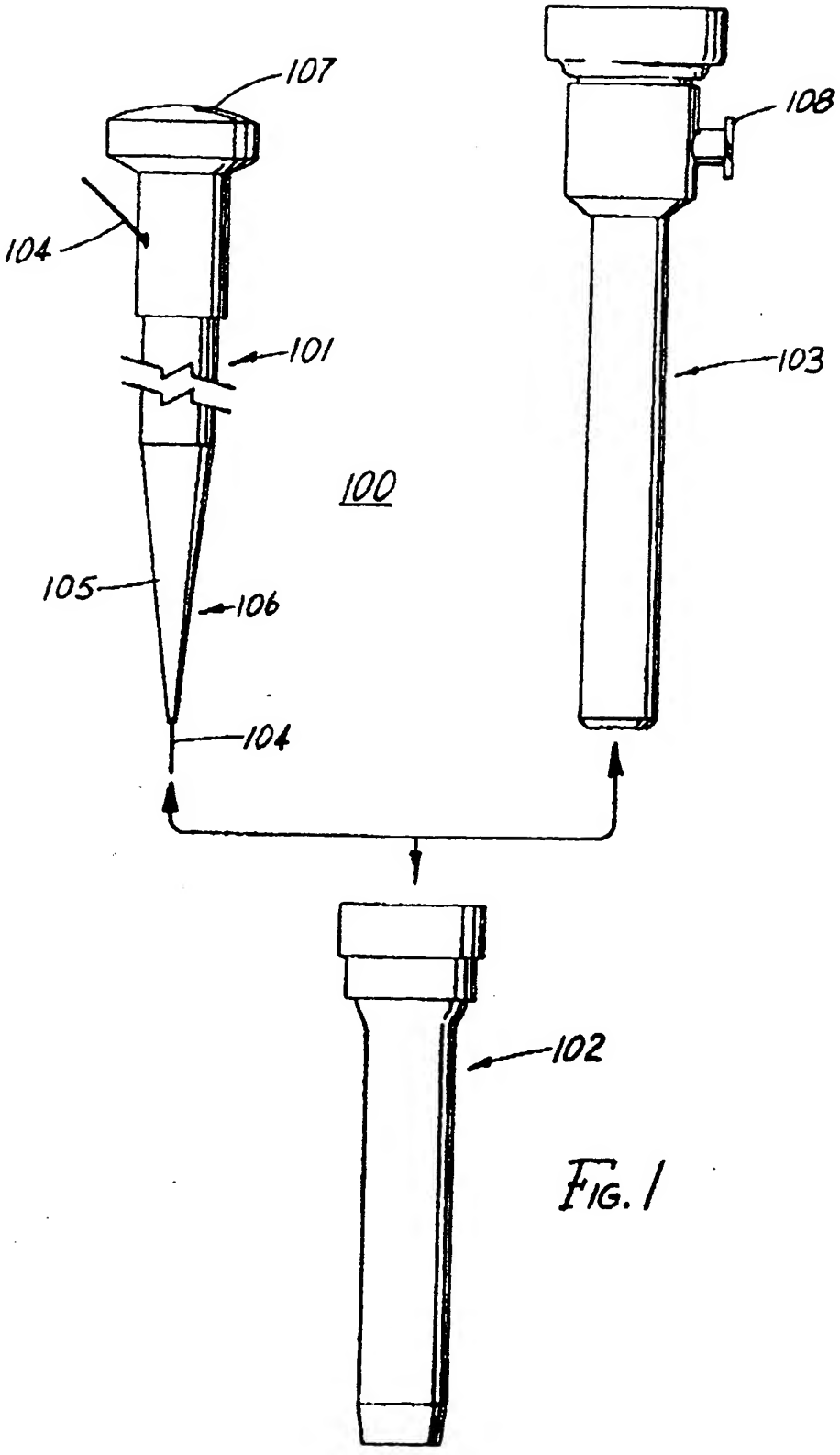

FIG. 1

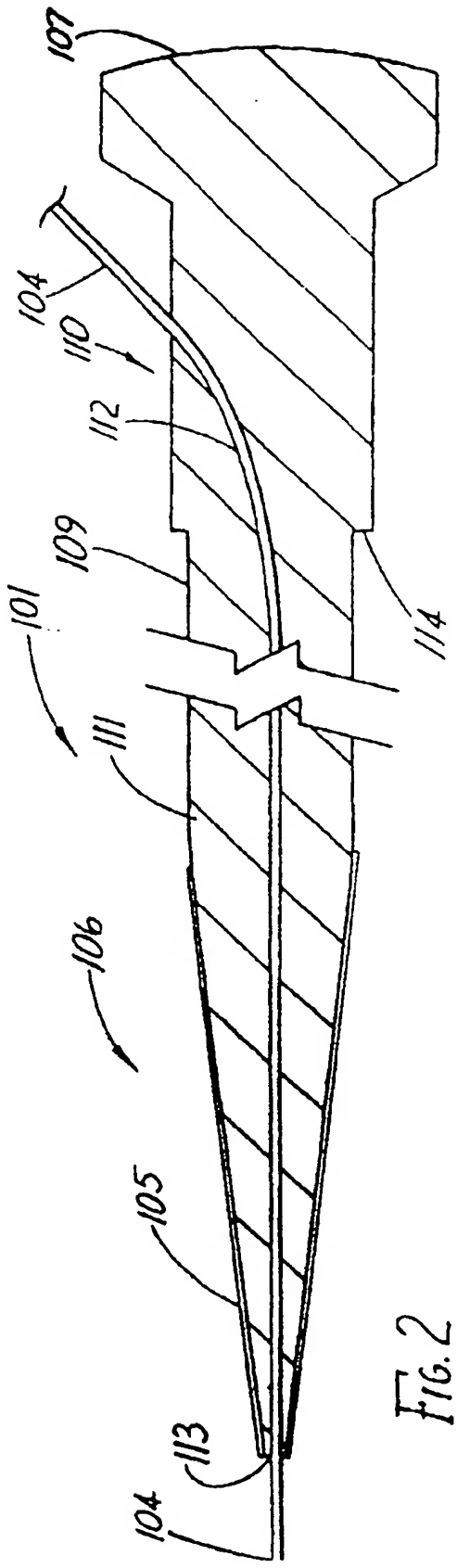

FIG. 2

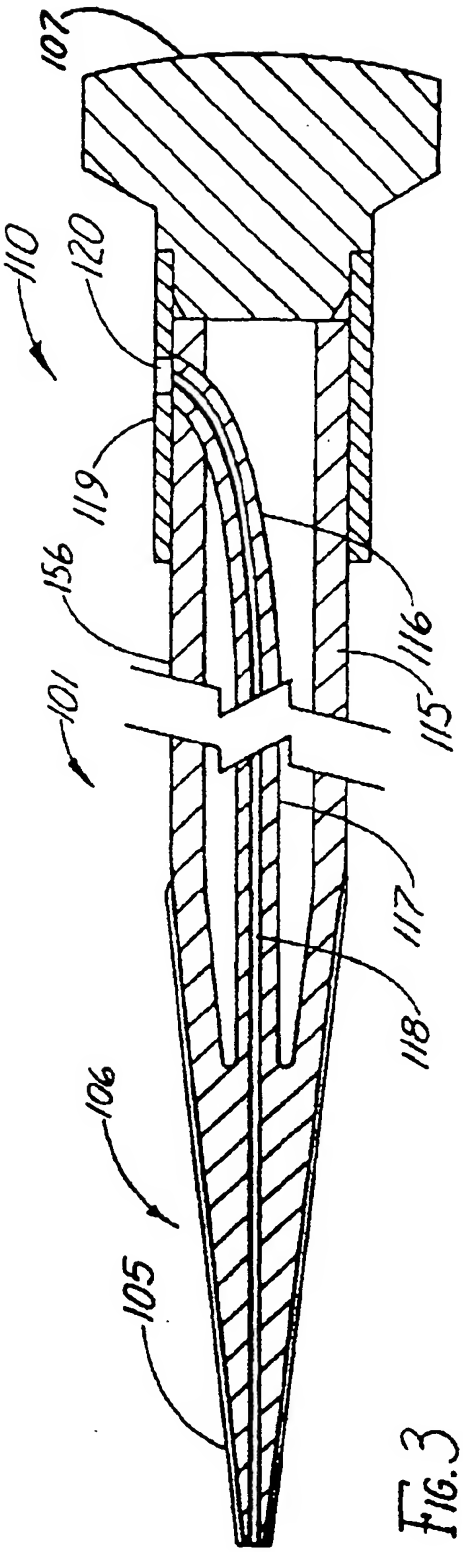

FIG. 3

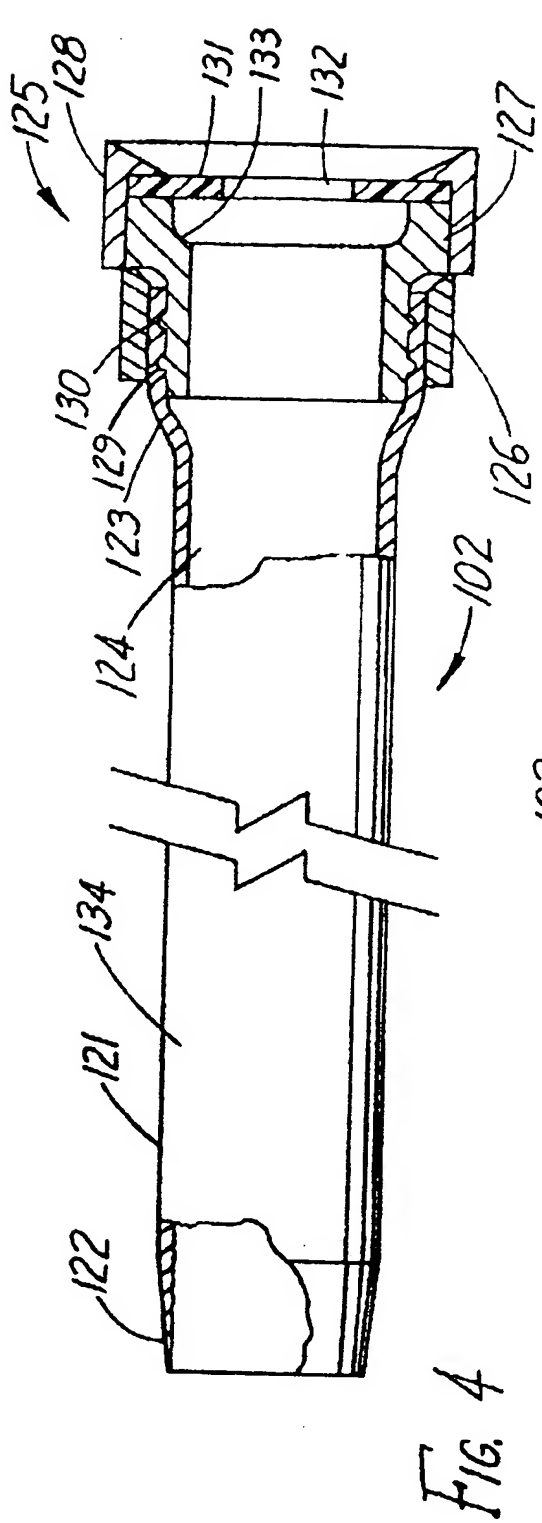

FIG. 4

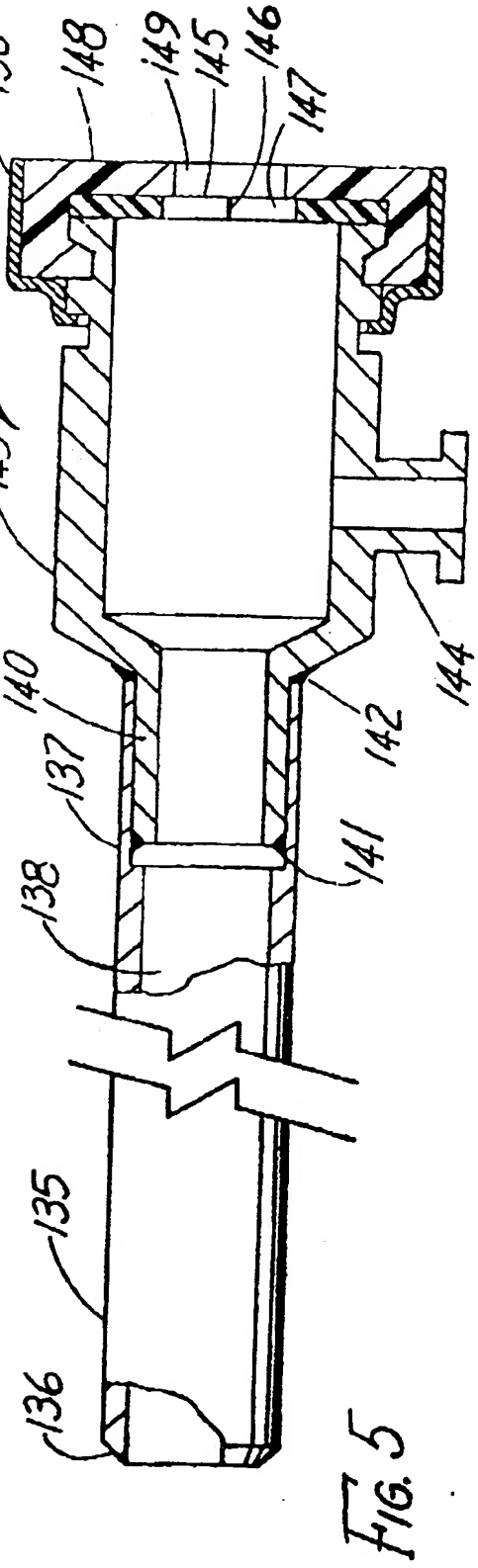

FIG. 5

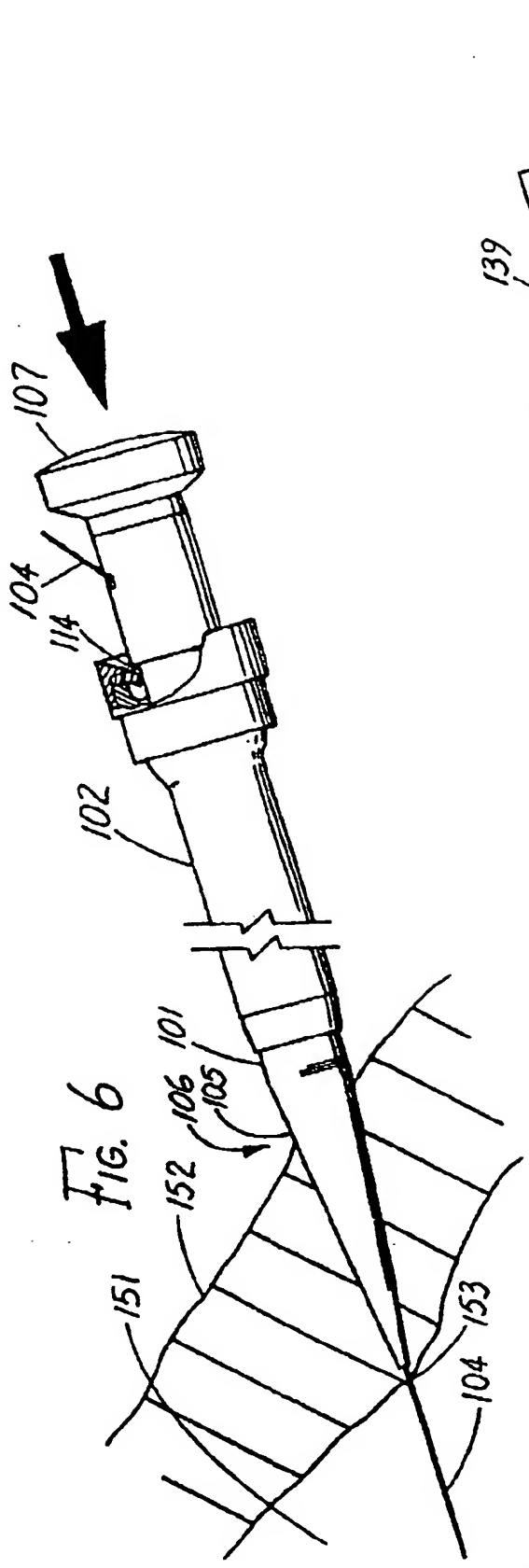

FIG. 6

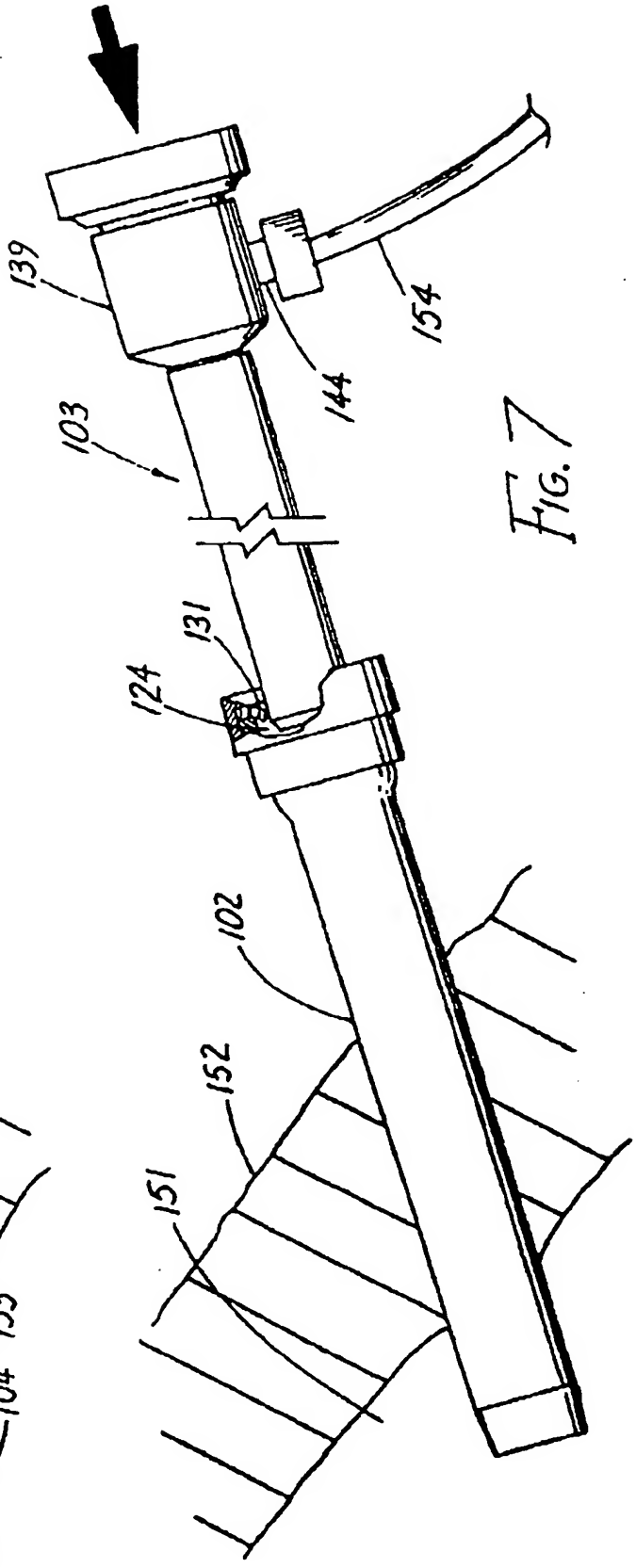

FIG. 7

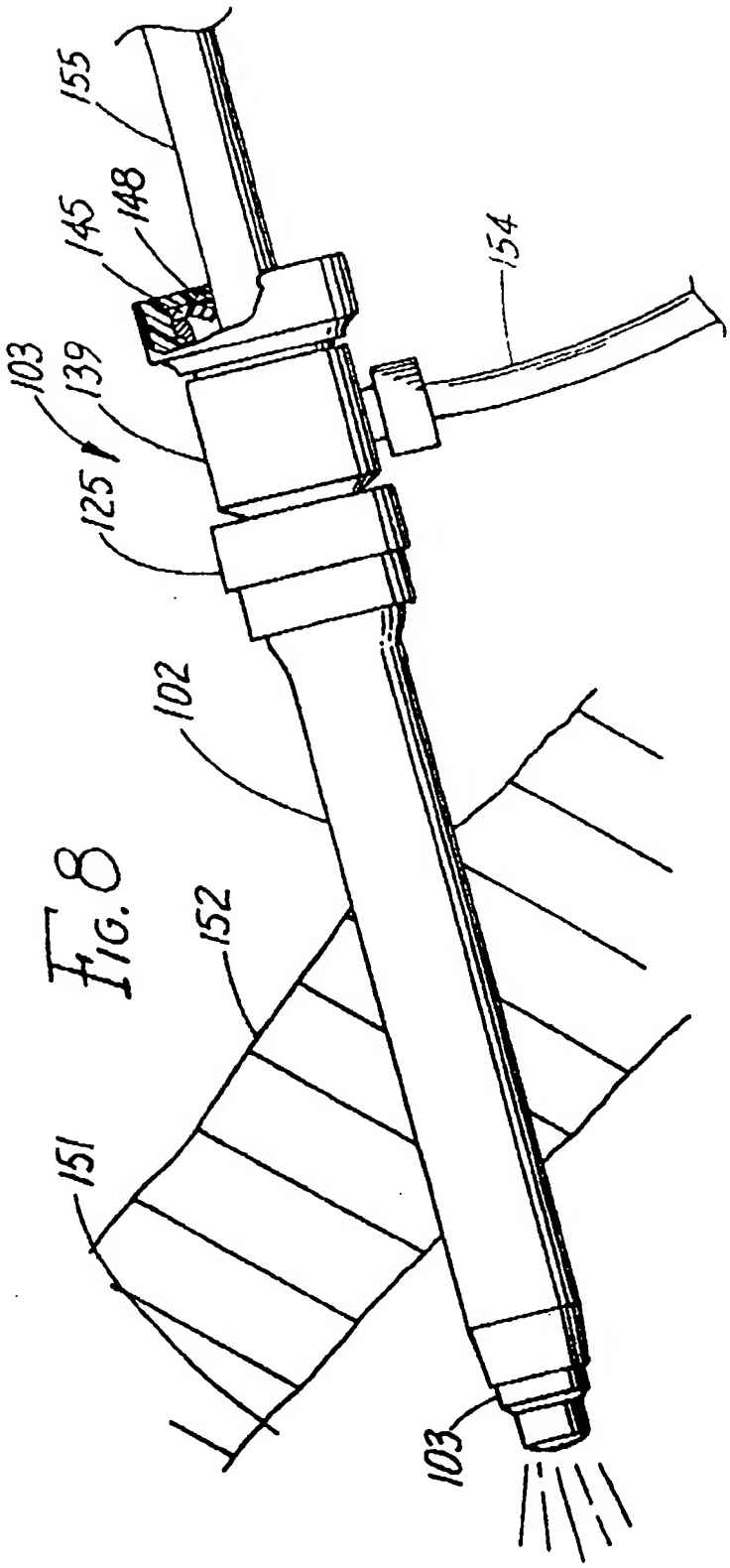

FIG. 8

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(88) Date of deferred publication of search report :
01.07.92 Bulletin 92/27

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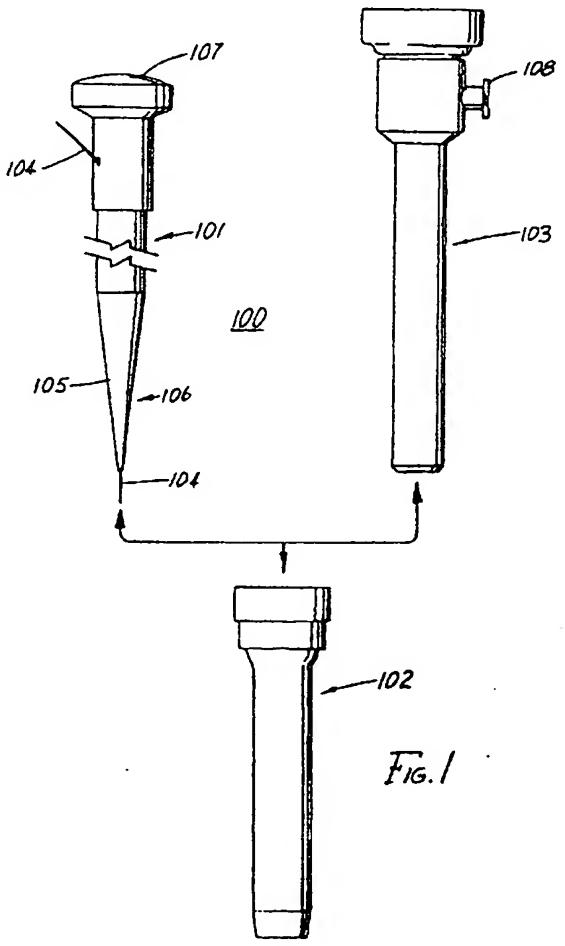

FIG. 1

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European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number EP 91 30 9012

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	EP-A-0 206 553 (STEVEN STREATFIELD) * Page 14, line 9 - page 15, line 5; page 16, line 6 - page 17, line 21; figures 6,11 *	1	A 61 B 17/34 A 61 M 29/00
Y		9	
X	US-A-4 498 902 (ASH et al.) * Column 2, line 62 - column 3, line 15; figures 1-3 *	2-5,10	
Y		9	
A	US-A-3 994 287 (TURP et al.) * Column 3, lines 31-46; column 4, lines 1-15; figures 1,3 *	2,3	
A	EP-A-0 339 945 (ADAIR) * Column 5, lines 38-58; figure 1 *	5	
A	DE-A- 836 546 (BERCHTOLD) * Page 2, lines 78-88; figure 7 *	1	
	-/-		

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 B
A 61 M

INCOMPLETE SEARCH

The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims

Claims searched completely :

Claims searched incompletely :

Claims not searched :

Reason for the limitation of the search:

see sheet -C-

Place of search	Date of completion of the search	Examiner
THE HAGUE	06-01-1992	MOERS R.J.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P0407)

European Patent Office

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

☐ All claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for all claims.

☐ Only part of the claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid,

namely claims:

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirement of unity of invention and relates to several inventions or groups of inventions,
namely:

see sheet -B-

☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid.

namely claims:

☒ None of the further search fees has been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims.

namely claims: 1-5,9,10

European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number
EP 91 30 9012

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
A	DERWENT WPIL, Derwent Publication Limited, London, GB; & JP-A-2 144 070 (PN) * Abstract *	10	TECHNICAL FIELDS SEARCHED (Int. Cl.5)

EPO FORM 1503 03.82 (P0410)

European Patent Office

EP 91 30 9012 -B-

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirement of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims 1-5,9,10 : Medical apparatus for endoscopic surgery comprising an elongated member having a tapered first distal end for penetrating and dilating a patient's skin.

2. Claims 6-8 : Medical apparatus for endoscopic surgery comprising an outer and an inner sheath.

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-C-

Claims searched completely: 1-5,9,10: Medical apparatus for endoscopic surgery

Claim not searched: 11:

Method for treatment of the human or animal body by surgery or therapy (see article 52(4) of the European Patent Convention)